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SCULLY SCOTT MURPHY & PRESSER, PC
400 GARDEN CITY PLAZA
SUITE 300
GARDEN CITY, NY 11530

EXAMINER	
TOWA, RENE T	

ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/761,962	TAKIZAWA ET AL.	
	Examiner	Art Unit	
	RENE TOWA	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,10,11 and 13-43* is/are pending in the application.

4a) Of the above claim(s) *3,11,13-28,30 and 32-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,10,29 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is responsive to an amendment filed January 13, 2009. Claims 2-3, 10-11 and 13-43 are pending. Claims 3, 11, 13-28, 30, 32-43 are withdrawn. Claims 2 & 29 have been amended. Claims 1, 4-9 and 12 have been cancelled.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. **Claims 2 & 29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bucalo (US 4,172,446) in view of Brockman (US 3,540,433), and further in view of Schuchardt et al. (US 4,206,000).

Bucalo discloses a swallowable medical capsule 10 having a magnet 56 therein such that when the capsule 10 is swallowed, it travels through the digestive system of a patient and gets discharged from the patient's body with feces; wherein the capsule 10 is conveniently removed from the feces by situating a permanent magnet adjacent the capsule 10 so that the magnet 56 responds to facilitate separation of the capsule from the feces (see abstract; see figs. 2 & 4; see col. 1, lines 56-68; col. 2, lines 1-17; col. 6, lines 46-62).

Bucalo disclose a system, as described above, that fails to explicitly teach a catch unit comprising a net made of a magnet or magnetic material.

However, **Brockman** discloses a medical strainer device 20 comprising a catch unit 24 for catching a sample that is discharged from a patient's body with feces (see figs. 1-5; col. 3, lines 1-5, 7-13 & 15-22; col. 5, lines 48-67). Brockman further discloses

a medical strainer device 20 wherein the catch unit 24 is a filtering net 36 (see figs. 1-5; col. 3, lines 1-5, 7-13 & 15-22; col. 5, lines 48-67).

Schuchardt et al. teach that it is known to provide filtering means with a magnet or magnetic material 23 for removing magnetic particles from a flow stream (see abstract; see fig. 1; see col. 3, lines 20-33).

Since both Bucalo and Brockman teach systems for the collection of biological samples that are discharged within a patient's feces for later analysis, it would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide the system of Bucalo with a retrieval device as taught by Brockman in order to facilitate the stool specimen collection by easily and simply mounting the device on a feces-receiving chamber such as a toilet bowl, bedpan, or the like such that the device may be easily washed and dried after use; moreover, before collecting the sample from the feces, it may be necessary to first collect the feces themselves.

Moreover, Bucalo teaches a medical capsule having a magnet such the capsule can be separated from the feces using a magnetic material; Brockman teaches a feces collection device that includes a screen for collecting the feces; since Schuchardt et al. teach that it is known to provide screens made from magnetic material to remove magnetic particles from a flow stream, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Bucalo as modified by Brockman above with a screen made of magnetic material as taught by Schuchardt et al. in order to facilitate separation of the capsule from the feces using the magnetic material. Moreover, since

a) one of ordinary skill in the art could have combined the teachings of Bucalo and Brockman with those of Schuchardt et al. as suggested in the rejections supra by known methods,

b) in the combination, each element (i.e. the strainer of Brockman and the magnetic characteristics of the screen of Schuchardt et al. following Bucalo's suggestion) in the combination would have performed the same function as it did separately; and,

c) one of ordinary skill in the art would have recognized that the results of the combination were predictable (i.e. rendering the screen of Brockman magnetic so as to attract the capsule of Bucalo for separation from the feces),

The Examiner submits that combining prior art elements according known methods to yield predictable results has recently been held to be obvious (see KSR International Co. v. Teleflex Inc., 550 U.S.---, 82 USPQ2d 1385 (2007)).

4. **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over Bucalo ('446) in view of Brockman ('433), Schuchardt et al. ('000), and further in view of Paulin (US 4,309,782).

Brockman as modified by Greutert discloses a system, as described above, that teaches all the limitations of the claim except for a bag to enclose the specimen together with a unit of the specimen retrieval device.

However, **Paulin** discloses a device comprising a bag 12 to enclose a specimen together with a catch unit 46 of the specimen retrieval device 16 for temporary storage

or transport, after the specimen has been collected (see abstract; see figs. 1-3; col. 2, lines 20-32 & 62-67).

Both Bucalo and Brockman teach systems for the collection of biological samples that are discharged within a patient's feces for later analysis at a laboratory or a physician's office; Brockman teaches a sample retrieval device for collecting the fecal specimen; since Paulin teaches a bag for a storing a medical retrieval device for temporary storage or transport to a physician's office or a laboratory, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Bucalo as modified by Brockman and Schuchardt et al. above with a bag as taught by Paulin in order to store and/or transport the collected specimen to a physician's office and/or laboratory.

5. **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over Bucalo ('446) in view of Brockman ('433), Schuchardt et al. ('000), and further in view of Slover et al. (US 4,445,235).

Bucalo as modified by Brockman and Schuchardt et al. discloses a system, as described above, that teaches all the limitations of the claim except for a bag to enclose the specimen together with a unit of the specimen retrieval device.

However, **Slover et al.** disclose a device comprising a bag to enclose a specimen together with a catch unit of the specimen retrieval device for temporary storage or transport, after the specimen has been collected (see column 4/lines 21-25).

Both Bucalo and Brockman teach systems for the collection of biological samples that are discharged within a patient's feces for later analysis at a laboratory or a

physician's office; Brockman teaches a sample retrieval device for collecting the fecal specimen; since Slover et al. teach a bag for a storing a medical retrieval device for temporary storage or transport to a physician's office or a laboratory, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Bucalo as modified by Brockman and Schuchardt et al. above with a bag as taught by Slover et al. in order to store and/or transport the collected specimen to a physician's office and/or laboratory.

6. **Claim 31** is rejected under 35 U.S.C. 103(a) as being unpatentable over Bucalo ('446) in view of Brockman ('433), Schuchardt et al. ('000), and further in view of Marshall (US 6,632,175).

Bucalo as modified by Brockman and Schuchardt et al. discloses a system, as described above, that fails to explicitly teach a system wherein the capsule is washed after capture.

However, **Marshall** teaches a system for retrieving a reusable medical capsule upon exiting the intestine through the rectum (i.e. via excrement) (see fig. 2; column 1/lines 44-46; column 3/lines 58-63).

The Examiner notes that since Marshall teaches a method wherein a reusable medical capsule is retrieved after discharge from a human body, the method inherently includes the step of washing the medical capsule with a washing unit (i.e. with gloves) since the steps of Marshall require, inter alia, swallowing the capsule "through the mouth" and discharging the capsule "through the rectum" (See Marshall, fig. 2; column 1/lines 44-46; column 3/lines 58-63).

Similarly, Brockman discloses a reusable medical retrieval device that is washed before re-use (see abstract; see col. 5, lines 68-75); as such, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Bucalo as modified by Brockman and Schuchardt et al. above, with a reusable capsule that is washed as suggested by Marshall in order to achieve a capsule that is in sanitary and sterile condition at the time of re-use or swallow. Moreover, since Bucalo teaches a medical capsule that collects sample specimen inside for later analysis, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Bucalo as modified by Brockman and Schuchardt et al. with a washing step as claimed in order to extract the collected sample within the capsule without contamination; for example, after the capsule is separated from the feces, it would be necessary to clean the capsule before attempt to collect the content thereof without contamination from the feces that otherwise would line the walls of the discharged capsule.

Response to Arguments

7. Applicant's arguments filed January 13, 2009 have been fully considered but they are not persuasive. Applicant argues that Schurchardt is non-analogous art and thus the combination of Schurchardt with Bucalo and Brockman is improper and should be withdrawn. This argument has been considered but has not been deemed persuasive.

In response the Applicant's argument, the Examiner respectfully traverses. For example, the Applicant argues that Schurchardt allegedly is non-analogous art because Schuchardt allegedly filters suspended magnetic particles in a bath and not from a flow

or stream being excreted from a body. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., separating magnetic particles from a flow or stream being excreted from a body) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Nonetheless, the Examiner observes that, as explained in the rejection supra, Schuchardt does teach a filter that is fully capable of separating magnetic particles from a flow or stream. For example, Schuchardt teaches that "the bath solution is effectively forced through the filter screen during both downward and subsequent upward displacement of the latter. As a result of such reciprocal displacement, any loose metallic debris in the bath is magnetically drawn against magnet-defined sites on the filter screen" (see abstract). As such, the Examiner submits that since filter is capable of magnetically drawing metallic debris from a bath solution that "is effectively forced through the filter screen," the filter is fully capable of separating magnetic particles from a flow or stream.

In response to applicant's argument that Schuchardt is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Schuchardt is related to the Applicant's field of endeavor because Schuchardt

pertains to grid-like filter screens (see figs. 2 & 4 of Schuchardt). Moreover, Schuchardt is also reasonably pertinent to the particular problem with which the applicant was concerned; for example, Schuchardt solves the problem of how to magnetically draw and separate minute metallic particles from a medium by proposing a magnetic filter screen (see abstract; see figs. 2 & 4). As such, the Examiner submits that, contrary to the Applicant's contention, Schuchardt is analogous art.

In view of the foregoing, the rejection over Schuchardt is maintained.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENE TOWA whose telephone number is (571)272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/R. T./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736